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REMARKS

The present application is directed to an antibody or a fragment thereof that recognizes a mammalian GBS toxin receptor or a fragment thereof. The application also describes a composition for detecting a GBS toxin receptor. Prior to this Response, Claims 82-89 and 97-103 were pending, with Claims 84 and 101 withdrawn from consideration as directed to non-elected subject matter. In this Response, applicants cancel Claims 84 and 101, amend the specification and Claims 82, 83, 85-89, 97-100, 102 and 103, and add new Claims 104 and 105. The amendments and the new claims do not add any new matter. Upon entry of the amendments, Claims 82, 83, 85-89, 97-100, and 102-105 will be pending.

Telephone Interview

Applicants thank the Examiner for the courtesy of the telephone interview on October \$\$, 2006.

Objection to the Disclosure

The Examiner objects to the specification because it does not reflect the status of the parent application Serial No. 09/359,167, now issued as U.S. Patent No. 6,803,448. Applicants have amended the specification to reflect the status of the parent application. The amendment does not introduce any new matter. In view of the amendment, applicants request withdrawal of the objection.

Claim Rejections under 35 U.S.C. §101

The Examiner rejects Claims 82, 83, and 85-89 under 35 U.S.C. §101, asserting that the claims are directed to non-statutory subject matter. Applicants assert that the amendment to Claim 82 overcomes the rejection. As suggested by the Examiner, applicants have amended independent Claim 82 to recite “[a]n isolated antibody.” Support for the amendment is found in the specification, for example, on page 25, lines 7-8, wherein a manual on the preparation of antibodies is incorporated by reference in its entirety into the specification,

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and also on page 45, line 19, wherein use of a claimed isolated antibody is disclosed. In view of the foregoing, applicants request withdrawal of the rejection under 35 U.S.C. §101.

Claim Rejections under 35 U.S.C. §112, First Paragraph

Enablement

The Examiner rejects Claims 82, 83, 85-89, 97-100, 102 and 103 under 35 U.S.C. §112, first paragraph, asserting that the specification does not provide sufficient enablement for the claims. Applicants assert that amendments to Claims 82 and 97 overcome the rejection.

The Examiner states that the specification is enabling for an antibody or a fragment thereof that binds the mammalian GBS toxin receptors set forth in SEQ ID NO:4 and SEQ ID NO:6, but asserts that the previously presented claims are overly broad. Applicants amend independent Claims 2 and 97 to recite "a mammalian GBS toxin receptor or a polypeptide fragment thereof, wherein the GBS toxin receptor has at least about 86% identity to SEQ ID NO:8." Support for the amendment is found throughout the specification, for example, on page 8, lines 23-32, where the term "polypeptide fragment" is defined, and also on page 17, first paragraph. Currently amended Claims 2 and 97 recite structural characteristics of a GBS toxin receptor or a fragments thereof as disclosed in the present application. Applicants respectfully assert that the application as filed enables one of ordinary skill in the art in the field of the present application to make and use antibodies as claimed in Claim 2 and compositions for detection of a mammalian GBS toxin receptor or a fragment thereof as claimed in Claim 97.

Applicants also respectfully assert that the Examiner's position expressed on p. 5 of the Office Action is not relevant to enablement of the pending claims. The Examiner states, "Since the disclosure fails to describe the conserved structure for the binding domain of GBS toxin receptor, it is unpredictable whether a fragment of GBS toxin receptor, for example, SEQ ID NO:8 maintains activity of the full-length receptor." Applicants bring to the Examiner's attention that it is not necessary for a fragment of a GBS toxin receptor to maintain activity of the full length receptor in order to make and use the claimed antibodies or compositions for detection of such fragment. As disclosed, for example, in Examples 3-5 on pp. 44-47 of the

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present application, an immunogenic fragment of a GBS toxin receptor can be used to generate the antibodies. Further, one of ordinary skill in the art in the field of the present application would be able to obtain a composition for detection of a GBS toxin receptor or a fragment thereof, for example, by screening for compounds capable of blocking antibody binding or GBS toxin binding to the GBS toxin receptors. The present application provides, starting on line 30, page 32 and through line 29, on p. 36, a number of procedures for identifying and using such compounds.

In view of the foregoing, applicants respectfully assert that application, as filed, enables one of ordinary skill in the art to make and use the compositions claimed in currently amended independent Claims 82 and 97, and their dependent Claims 83, 85-89, 98-100, 102 and 103. Applicants request withdrawal of the rejection under 35 U.S.C. §112, 1st paragraph, for reasons of insufficient enablement.

Written Descriptions

The Examiner rejects Claims 82, 83, 85-89, 97-100, 102 and 103 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Applicants assert that amendments to Claims 82 and 97 submitted in this Response overcome the rejection.

The Examiner asserts that the claims, as previously presented, "do not require that the GBS toxin receptor or a fragment thereof possess any particular conserved structure or disclosed distinguishing feature." In this Response, applicants amend Claims 82 and 97 to recite "a mammalian GBS toxin receptor or a polypeptide fragment thereof, wherein the GBS toxin receptor has at least about 86% identity to SEQ ID NO:8." Support for the amendment found in the specification is discussed in the previous section. Currently amended claims recite distinguishing features of a genus of GBS toxin receptors or fragments thereof disclosed in the application, as filed, in such a way as to reasonably convey to one skilled in the art in the field of

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the present application that the inventor, at the time the application was filed, had possession of the claimed invention. In view of the foregoing, applicants request withdrawal of the rejection under 35 U.S.C. §112, first paragraph, for reasons of insufficient written description.

Claim Rejections under 35 U.S.C. §112, Second Paragraph

The Examiner rejects Claims 82, 83, 85-89, 97-100, 102 and 103 under 35 U.S.C. §112, second paragraph, as indefinite because they recite "GBS toxin receptor." The Examiner asserts that the term is determined arbitrarily without a definitive structure, and that applicants should particularly point out and distinctly recite characteristics associated with the protein, such as a sequence identifier. As discussed above, applicants amend Claims 82 and 97 to recite "a mammalian GBS toxin receptor or a polypeptide fragment thereof, wherein the GBS toxin receptor has at least about 86% identity to SEQ ID NO:8." Accordingly, currently amended claims recite characteristics associated with the protein recited in the claims, including an appropriate sequence identifier.

Further, the Examiner asserts that Claim 97 is indefinite because it recites the term "a reagent." The Examiner states that the specification fails to define the term unambiguously. Applicants respectfully bring to the Examiner's attention that the term "reagent" in relation to detection of GBS toxin receptor is defined in the specification, for example, on p. 41, lines 28-33.

In view of the foregoing, applicants assert that Claims 82, 83, 85-89, 97-100, 102 and 103 are definite and request withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Claim Objections – Minor Informality

The Examiner objects to Claims 82, 83, 85-89, 97-100, 102 and 103. The Examiner asserts that Claims 83, 85-89, 989-100, 102 and 103 depend from cancelled claims, and that Claims 83, 85-89, 98-100, 102 and 103 recite non-elected subject matter. Applicants amend Claims 83, 85-89, 989-100, 102 and 103 to correct their dependency. Applicants amend

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Claims 83 and 100 to delete non-elected SEQ ID NO:4 and cancel Claims 84-101. Applicants further bring to the Examiner's attention that Claims 82 and 97 are amended to recite elected SEQ ID NO:8. Applicants therefore request withdrawal of the objection to the claims due to minor informalities

New claims

Applicants add new claims 104 and 105. The claims are supported by the specification, for example, on pp. 45-48 of the present application (Examples 4-6) and incorporate all limitations of independent Claim 82. Applicants request favorable consideration and allowance of the new claims.

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CONCLUSION

The foregoing is submitted as a complete Response to the Office Action mailed July 20, 2006. Applicants submit that the claims in the present application are in condition for allowance, and such action is courteously solicited. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 11-0855. If the Examiner believes that any informalities remain in the case, which may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned agent at (404) 815-6102 is respectfully solicited.

Respectfully submitted,



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